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10/635,402	08/06/2003	Edward S. Ahn	220318	1210
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EXAMINER				
SOROUSH, ALI				
ART UNIT		PAPER NUMBER		
1616				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Chgpatent@leydig.com

Office Action Summary

Application No.

10/635,402

Applicant(s)

AHN, EDWARD S.

Examiner

ALI SOROUSH

Art Unit

1616

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 69, 70 and 78-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 69, 70, and 78-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Office Action mailed on 02/22/2010 is hereby vacated since the Examiner did not clearly address the 1,132 Declaration submitted by Dr. Ahn on 10/26/2009. This Office Action is hereby set forth to respond to all remarks submitted by Applicant on 10/26/2009 to the Office Action mailed on 06/24/2009.

Acknowledgement of Receipt

Applicant's response filed on 10/26/2009 to the Office Action mailed on 06/24/2009 is acknowledged.

Status of the Claims

Claims 1, 69, and 70 are currently amended, claims 80-85 are newly added, and claims 18-68 and 71-77 are cancelled. Claims 1-17, 69, 70, and 78-85 are currently pending examination for patentability.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.

3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. The rejection of claims 1-7, 12-14, 17, 69-70, 78, and 79 under 35 U.S.C. 103(a) as

being unpatentable over Kawamura et al. (US Patent 4717556, Published 01/05/1988) in view of Tanaka et al. (US Patent 6441073 B1, Published 08/27/2002) **is maintained**.

Applicant Claims

A composition comprising particulate tricalcium phosphate having an average particle size of about 5 μm or less, an average crystal size of about 250 nm or less, and surface area of about 20 m^2/g or greater, wherein the composition can be consolidated to form a TCP article having a compressive strength of about 50 MPa or greater. The composition may further comprise a secondary additive such as a structural additive, organic species, or biological additive.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Kawamura et al. teach, "A microfine β -tricalcium phosphate powder is produced ..." (See abstract). "The dry powder of β -tricalcium phosphate obtained by the method of this invention has a specific surface area of 70 to 100 m^2/g . When this powder is calcined at 750°C, for example, the resulting powder still has a very large specific surface area on the order of 30 m^2/g ." (See column 4, Lines 1-16). "The aforementioned dry powder ... is converted into clear crystals at 750°C. The crystals ... closely resemble spheres about 0.1 micron in diameter." (See column 4, Lines 18-23) "In ... the case of foliate particles, the particles which have undergone the calcination have a specific surface area of 30 m^2/g , for example, and the sintered mass

produced from this calcinated particles exhibits bending strength in the range of 1,350 to 1,460 kgf/cm². The product of this invention, thus, is superior to the conventional product.” (See column 3, Lines 22-28). Kawmura et al. further teach, “The sintered articles of the β -tricalcium phosphate which is obtained by the method of this invention exhibit highly desirable strength and, therefore, are suitable for use as bioceramics including artificial bones, artificial joints, and artificial roots.” (See column 4, Lines 33-37).

*Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)*

Kawmura et al. lacks a teaching of a tricalcium phosphate (TCP) having a particle size of 5 μ m or less. Further, Kawmura et al. also lacks a composition of TCP further comprising a secondary additive. These deficiencies are cured by the teachings of Tanaka et al.

Tanaka et al. teaches a biomaterial for induction of osteoanagenesis comprising a copolymer of lactic acid, glycolic acid, and capralactone and tricalcium phosphate. The ratio of the TCP to polymer is 1:0.1 to 1:2. The TCP particle size to be used should be in the range of 0.1 to 200 μ m and can be sintered at 650 to 1500°C to provide for a denser particle. (See column 16, claims 1, 2; column 18, claims 12-14; column 8, Lines 1 and 40-43). “When average particle size is less than 0.1 μ m, the dissolving rate is too quick to show sufficient tissue reconstructing ability and ... on the contrary when the average particle size is more than 200 μ m, the dissolving rate becomes to slow whereby the tissue reconstruction is inhibited ...” (See column 7, Lines 57-63). “It is preferred that the rigidity of the osteogenesis inducing material of the present invention is adjusted to 200-20000 Mpa ...” (See column 6, Lines 25-27). “It is also possible that pharmaceuticals such as physiological substances including anti-tumor agent, anti-cancer agent,

anti-inflammatory agent, vitamins (for example, vitamin D of an activated type) and polypeptides (for example a thyroid stimulating hormone) are added to the complex to give sustained release function whereby the tissue regeneration and the bone tissue repair are promoted ..." (See column 8, Lines 51-57).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Kawamura et al. with Tanaka et al. One would have been motivated to do so because Tanaka et al. teaches that TCP particle size is important in ensuring that TCP does not dissolve too fast or dissolve so slow as to inhibit tissue reconstruction. Therefore, one of ordinary skill in the art would have been motivated to form the TCP articles of Kawamura et al. into particle sizes of 0.1 to 200 μm , which reads on the instantly claimed less than 1 μm . With regard to the addition of a secondary additive, Kawamura et al. makes obvious the addition of both a polymer additive as well as a pharmaceutical additive. The addition of polymer additive would enhance the strength of the TCP article and the addition of the pharmaceutical would promote tissue regeneration where the article is implanted. With regard to the limitations of the compressive strength and densification, it is noted by the examiner that the limitations read "can be" is optional claim language and therefore is not a limitation that prior art needs to teach or suggest. Kawamura et al. and Tanaka et al. are silent with regard to the compressive strength and the ability of TCP being made dense, however since the TCP of the prior art and the TCP of instant claims are not structurally indistinguishable it is the Examiner's position that the prior art TCP would inherently have the same properties. For the foregoing reasons, the instant composition would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Response to Applicant's Arguments

Applicant argues that one of ordinary skill in the art would not have been motivated to modify the particle size of TCP taught by Kawamura et al. to 5µm or less. Applicant's argument has been fully considered but found not to be persuasive. One would have been motivated to adjust the size of the particle size of TCP taught by Kawamura et al. because Tanaka et al. teaches that TCP particle size is important in ensuring that TCP does not dissolve too fast or dissolve so slow as to inhibit tissue reconstruction.

Applicant argues that the amendment positively reciting "TCP is densified to form an article having a minimum dimension of about 0.5cm or greater, the article transmits about 50% or more light ..." is not taught by the teachings of Kawamura et al. and Tanaka et al. Applicant's argument has been fully considered but found not to be persuasive. Kawamura et al. teach that the TCP particles can be densified. It would have been obvious to adjust the size of the article to 0.5cm or greater through routine optimization of the article for different uses. With regard to the light transmittance, it is the Examiners position such a property is inherent to the article made obvious by the teachings of Kawamura et al. and Tanaka et al. For the foregoing reasons, the rejection of claims 1-7, 12-14, 17, and 69-70 under 35 U.S.C. 103(a) is maintained.

2. The rejection of claims 8-11 under 35 U.S.C. 103(a) as being unpatentable over Kawamura et al. (US Patent 4717556, Published 01/05/1988) in view of Tanaka et al. (US Patent 6441073 B1, Published 08/27/2002) further in view of Kijima et al. (US Patent 5185177, Published 02/09/1993) **is maintained.**

Applicant Claims

A composition comprising particulate tricalcium phosphate having an average particle size of about 5 μm or less, an average crystal size of about 250 nm or less, and surface area of about 20 m^2/g or greater, wherein the composition can be consolidated to form a TCP article having a compressive strength of about 50 Mpa or greater. The composition may further comprise a secondary additive such as a structural additive, organic species, or biological additive.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The combined teachings of Kawamura et al. and Tanaka et al. are disclosed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

The combined teachings of Kawamura et al. and Tanaka et al. lack a teaching where the secondary additive is a structural additive. These deficiencies are cured by the teachings of Kijima et al.

Kijima et al. teaches a ceramic implant comprising α -tricalcium phosphate and zirconia. "The present inventors have conducted extensive researches in view of the above problems. As a result, they have found that a ceramic implant having a coating layer of a porous sintered body of a mixture of α -TCP and zirconia, or hydroxyl apatite and zirconia, on the surface of a sintered body of zirconia, has high mechanical strength and is free from breakage in a living body, and the biologically active surface porous layer bonded firmly to the core material, is capable of bonding to vital tissue in the living body, whereby it can be a material durable for use for a long period of time." (See column 1, Lines 49-59).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Kawamura et al. and Tanaka et al. with Kijima et al. One would have been motivated to combine the implants of Tanaka et al. and Kijima et al. so as to provide an implant that has both osteoagenic properties as well as increased mechanical strength. Therefore, a TCP implant composition having high mechanical strength and osteoagenic properties would have been obvious to one of ordinary skill in the art. For the foregoing reasons, the instant composition would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Response to Applicant's Arguments

Applicant argues that the deficiencies of the teachings of Kawamura et al. and Tanaka et al. discussed above are not cured by the teachings of Kijima et al. Applicant's argument has been fully considered but not found to be persuasive. As discussed above the deficiencies Applicant argues that are not cured by Kijima et al. are suggested by the teachings of Kawamura et al. and Tanaka et al. For the foregoing reasons, the rejection of claims 8-11 under 35 U.S.C. 103(a) is maintained.

3. The rejection of claims 15 and 16 under 35 U.S.C. 103(a) as being unpatentable over Kawamura et al. (US Patent 4717556, Published 01/05/1988) in view of Tanaka et al. (US Patent 6441073 B1, Published 08/27/2002) further in view of Dalal et al. (US Patent 6949251, Published 09/27/2005, Filed 09/21/2001) **is maintained.**

Applicant Claims

A composition comprising particulate tricalcium phosphate having an average particle size of about 5 μm or less, an average crystal size of about 250 nm or less, and surface area of about 20 m^2/g or greater, wherein the composition can be consolidated to form a TCP article having a compressive strength of about 50 Mpa or greater. The composition may further comprise a secondary additive such as a structural additive, organic species, or biological additive.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The combined teachings of Kawamura et al. and Tanaka et al. are disclosed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

The combined teachings of Kawamura et al. and Tanaka et al. lack a teaching where the secondary additive is a biological additive. These deficiencies are cured by the teachings of Dalal et al.

Dalal et al. teaches, “A composition comprising porous β -tricalcium phosphate (β -TCP) granules that have a particle size of 0.1 –2 mm and that comprise a multiplicity of pores ...” (See column 59, claim 1). “The composition of any one of claims 1 to 5, further comprising a bioactive agent.” (See column 59, claim 13). “The composition of claim 13, wherein the bioactive agent is a bone morphogenic protein.” (See column 59, claim 14). “The composition of claim 13, wherein the bioactive agent is an osteogenic protein ...” (See column 59, claim 16). “The invention also provides an implantable prosthetic device ...” (See abstract).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kawamura et al. and Tanaka et al. with Dalal et al. One would have been motivated to do so to provide for a more efficient implant that induces osteoanagesis. Both the Tanka et al. implant and the Dalal et al. teach inducing osteoagenesis and the combination of the two would have been obvious because it would have provided an additive osteoagenesis effect. For the foregoing reasons the instant compositions would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Response to Applicant's Arguments

Applicant argues that the deficiencies of the teachings of Kawamura et al. and Tanaka et al. discussed above are not cured by the teachings of Dalal et al. Applicant's argument has been fully considered but not found to be persuasive. As discussed above the deficiencies Applicant argues that are not cured by Dalal et al. are suggested by the teachings of Kawamura et al. and Tanaka et al. For the foregoing reasons, the rejection of claims 8-11 under 35 U.S.C. 103(a) is maintained.

Response to the 1.132 Declaration

Dr. Ahn argues that the TCP formation can be adversely affected by several factors and in particular the presence of impurities. Further, Dr. Ahn indicates chemico-mechanical process often contain significant impurities. Dr. Ahn's arguments have been fully considered but found not to be persuasive. The Declaration by Dr. Ahn does not provide any data to support the argument that the Kawamura et al. particulate TCPs have impurities or that it does not result in having the properties instantly claimed. For the foregoing reasons, the 1.132 Declaration is not found to be persuasive.

New Grounds of Rejection

4. Claims 80-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawamura et al. (US Patent 4717556, Published 01/05/1988) in view of Tanaka et al. (US Patent 6441073 B1, Published 08/27/2002).

Applicant Claims

A composition comprising particulate tricalcium phosphate having an average particle size of about 5 μm or less, an average crystal size of about 250 nm or less, and surface area of about 20 m^2/g or greater, wherein the composition can be consolidated to form a TCP article having a compressive strength of about 50 MPa or greater. The composition may further comprise a secondary additive such as a structural additive, organic species, or biological additive.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Kawamura et al. teach, "A microfine β -tricalcium phosphate powder is produced ..." (See abstract). "The dry powder of β -tricalcium phosphate obtained by the method of this invention has a specific surface area of 70 to 100 m^2/g . When this powder is calcined at 750°C, for example, the resulting powder still has a very large specific surface area on the order of 30 m^2/g ." (See column 4, Lines 1-16). "The aforementioned dry powder ... is converted into clear crystals at 750°C. The crystals ... closely resemble spheres about 0.1 micron in diameter." (See column 4, Lines 18-23) "In ... the case of foliate particles, the particles which have undergone the calcination have a specific surface area of 30 m^2/g , for example, and the sintered mass produced from this calcinated particles exhibits bending strength in the range of 1,350 to 1,460 kgf/cm^2 . The product of this invention, thus, is superior to the conventional product." (See

column 3, Lines 22-28). Kawmura et al. further teach, "The sintered articles of the β -tricalcium phosphate which is obtained by the method of this invention exhibit highly desirable strength and, therefore, are suitable for use as bioceramics including artificial bones, artificial joints, and artificial roots." (See column 4, Lines 33-37).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Kawmura et al. lacks a teaching of a tricalcium phosphate (TCP) having a particle size of 5 μm or less. Further, Kawmura et al. also lacks a composition of TCP further comprising a secondary additive. These deficiencies are cured by the teachings of Tanaka et al.

Tanaka et al. teaches a biomaterial for induction of osteoanagenesis comprising a copolymer of lactic acid, glycolic acid, and caprolactone and tricalcium phosphate. The ratio of the TCP to polymer is 1:0.1 to 1:2. The TCP particle size to be used should be in the range of 0.1 to 200 μm and can be sintered at 650 to 1500°C to provide for a denser particle. (See column 16, claims 1, 2; column 18, claims 12-14; column 8, Lines 1 and 40-43). "When average particle size is less than 0.1 μm , the dissolving rate is too quick to show sufficient tissue reconstructing ability and ... on the contrary when the average particle size is more than 200 μm , the dissolving rate becomes to slow whereby the tissue reconstruction is inhibited ..." (See column 7, Lines 57-63). "It is preferred that the rigidity of the osteogenesis inducing material of the present invention is adjusted to 200-20000 MPa ..." (See column 6, Lines 25-27). "It is also possible that pharmaceuticals such as physiological substances including anti-tumor agent, anti-cancer agent, anti-inflammatory agent, vitamins (for example, vitamin D of an activated type) and polypeptides (for example a thyroid stimulating hormone) are added to the complex to give

sustained release function whereby the tissue regeneration and the bone tissue repair are promoted ..." (See column 8, Lines 51-57).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Kawamura et al. with Tanaka et al. One would have been motivated to do so because Tanaka et al. teaches that TCP particle size is important in ensuring that TCP does not dissolve too fast or dissolve so slow as to inhibit tissue reconstruction. Therefore, one of ordinary skill in the art would have been motivated to form the TCP articles of Kawamura et al. into particle sizes of 0.1 to 200 μm , which reads on the instantly claimed less than 1 μm . Kawamura et al. and Tanaka et al. are silent with regard to the light transmission and the ability of TCP being made dense, however since the TCP of the prior art and the TCP of instant claims are not structurally indistinguishable it is the Examiner's position that the prior art TCP would inherently have the same properties. For the foregoing reasons, the instant composition would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/635,402

Page 15

Art Unit: 1616

Ali Soroush
Patent Examiner
Art Unit: 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616